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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------|------------------------------|----------------------|---------------------|------------------|
| 10/623,466 | 07/18/2003 | Gary S. Dixon | 976626-100/001 | 2973 |
| 29484 PATENTMETI | 7590 06/10/200 RIX | 9 | EXAMINER | |
| | R DR. BOX 914 | CHENG, JACQUELINE | | |
| IRVINE, CA 92604 | | | ART UNIT | PAPER NUMBER |
| | | | 3768 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 06/10/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

hazim@patentmetrix.com sona@patentmetrix.com

| | Application No. | Applicant(s) | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------------|--|--|--|--|
| Office Action Commence | 10/623,466 | DIXON ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | JACQUELINE CHENG | 3768 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 16 Fe | ebruary 2009 | | | | | |
| | action is non-final. | | | | | |
| · <u> </u> | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| ologod in adderdance with the practice under E | x parte gaayle, 1000 C.D. 11, 10 | 0.0.210. | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 44-61 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 44-61 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ acce | epted or b) objected to by the E | Examiner. | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correct | ion is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some coll None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 4) Interview Summary (PTO-413) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other: | | | | | | |

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed February 16, 2009 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's arguments that the combination of Lang (US 2003/0015208) and Faulkner (US 6,740,041) does not show a prima facie obviousness of the claimed invention. The examiner has considered all of the words in the claim, however since there are "if" statements in the claim the combination of Lang and Faulkner reads on the claim. Lang and Faulkner read on the claim in the situation where if the T-score is not abnormal. In the situation where the T-score is normal the claimed method continues to the prescribing a therapy and designating a future time. Lang and Faulkner discloses all of these steps of measuring a bone characteristic (bone mineral density) to yield a T-score, prescribing a therapy based upon a T-score, and repeating the measurement at a future time. In this situation where the T-score is normal the method does not involve measuring either gait or bone marker so therefore Lang and Faulkner do not need to teach measuring either gait, or bone marker, or both. It is therefore believed that the rejection dated July 9, 2008 still stands and is repeated below with a few newly noticed claim objections.

Claim Objections

2. Claim 44 is objected to because the claim is incomplete. The claim states it is a "method for treating a patient" yet has no treating steps. It is suggested that either the claim preamble be

of treating a patient. Appropriate correction is required.

amended to read --a method for prescribing a therapy—or the claim be amended by adding a step

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3. Claim 44 is also objected to because a future time for repeating each of the measurements of bone characteristic level, gait analysis and bone marker concentration is not always designated. The future time is only designated for repeating the measurements that have been measured (for example if you do not perform a gait analysis you cannot set a future time to *repeat* the gait analysis).

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 44-47, 51-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang (US 2003/0015208 A1) in view of Faulkner (US 6,740,041 B2).
- 6. Claims 44, 45, 51-58: Lang teaches a method to diagnose treat and prevent bone loss. In Lang a bone characteristic level such as bone mineral density is measured and therapy is prescribed based on the bone mineral density (abstract, paragraph 0030). Repeat measurements of the bone characteristic is taken over a period of time, which can be seconds, minutes, hours, days, months, or any interval there between (paragraph 0067). Lang does not explicitly disclose using a T-score as a measure of the bone mineral density, however it is well known in the art as disclosed by Faulkner that a raw bone mineral density value has limited meaning to a physician

(col. 1 line 27-35) so it is obvious to provide an established reference such as a T-score to make the raw bone mineral density value of Lang useful. If the measurements of Lang results in a normal T-score, then a therapy such as a postponement of development of bone loss symptom can be prescribed such as taking a calcium supplement (paragraph 0023).

- 7. **Claims 46, 47, 59-61:** These claims are rejected under Lang as well as according to broadest reasonable interpretation there is no measuring of a gait characterization or bone marker concentration so therefore these steps therefore are not required.
- 8. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang in view of Faulkner, and further in view of Chaintreuil (US 6,234,969 B1). Chaintreuil discloses a bone densitometer having a housing for a foot in which a pair of ultrasonic transducers engages the heel at a controlled pressure. The ultrasonic waves that are detected are the used to calculate an quantitative ultrasound index, or a stiffness value (fig. 1, col. 4 line 14-61). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Chaintreuil with Lang as Lang discloses using ultrasound measurements for the imaging test.

Conclusion

- 9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.
- 12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Long V Le/ Supervisory Patent Examiner, Art Unit 3768